CLAIMS

What is claimed:

1. A flow control device for a bronchial passageway, comprising:

a valve member that regulates fluid flow through the flow control device, the valve having a default shape;

a frame coupled to the valve member, the frame including:

a valve protector region that at least partially surrounds the valve member to maintain the default shape; and

a retainer region connected to the valve protector region, the retainer region being formed of a plurality of interconnected struts configured to engage an interior wall of the bronchial passageway to retain the flow control device in a fixed location therein, the retainer region being movable from a contracted state suitable for introduction into the bronchial passageway to an expanded state suitable for engaging the interior wall of the bronchial passageway; and

a membrane covering at least a portion of the retainer region, wherein at least a portion of the flow control device forms a seal with the interior wall of the bronchial passageway when the flow control device is implanted in the bronchial passageway, and wherein the membrane provides a fluid pathway from the seal to the valve member to direct fluid flowing through the bronchial passageway into the valve member.

2. A flow control device as defined in claim 1, wherein the membrane covers the entire retainer region of the frame.

3. A flow control device as defined in claim 1, wherein the membrane covers the retainer region of the frame and the valve protector region of the frame.

4. A flow control device as defined in claim 1, wherein the struts of the frame are arranged to form a plurality of cells, and wherein the cells are covered by the membrane.

5. A flow control device as defined in claim 1, wherein the frame comprises a superelastic material.

6. A flow control device as defined in claim 1, wherein the valve member limits fluid flow in an inhalation direction and permits fluid flow in the exhalation direction.

7. A flow control device as defined in claim 1, wherein the valve member blocks fluid flow in an inhalation direction and permits fluid flow in an exhalation direction.

8. A flow control device as defined in claim 1, wherein the valve member blocks fluid flow in both an inhalation direction and in an exhalation direction.

9. A flow control device as defined in claim 1, wherein the valve member comprises a duckbill valve having a pair of opposed walls having edges that form

opposed lips of a mouth, wherein the walls can move with respect to one another to open and close the mouth.

10. A flow control device as defined in claim 9, wherein the lips of the mouth are curved.

11. A flow control device as defined in claim 9, wherein the lips of the mouth are straight.

12. A flow control device as defined in claim 9, wherein the opposed walls have domed outer surfaces.

13. A flow control device as defined in claim 9, wherein the opposed walls have flat outer surfaces.

14. A flow control device as defined in claim 9, wherein a flow channel is located between the lips of the valve mouth.

15. A flow control device as defined in claim 1, wherein the valve protector region comprises a tube.

16. A flow control device as defined in claim 15, wherein the tube has at least one window formed therein.

17. A flow control device as defined in claim 15, wherein the tube is non-expandable.

18. A flow control device as defined in claim 1, wherein the valve protector region comprises a plurality of struts.

19. A flow control device as defined in claim 1, wherein the valve protector region is flexible.

20. A flow control device as defined in claim 1, wherein the valve protector region is rigid.

21. A flow control device as defined in claim 1, wherein the valve protector region and the retainer region are formed from a single piece of material.

22. A flow control device as defined in claim 21, wherein the single piece of material comprises a tube.

23. A flow control device as defined in claim 1, wherein the valve protector region and the retainer region are composed of the same material.

24. A flow control device as defined in claim 23, wherein the material is metal.

25. A flow control device as defined in claim 1, wherein the struts form a series of undulating loops in the contracted state.

26. A flow control device as defined in claim 25, wherein the undulating loops form a series of zig-zags in the expanded state.

27. A flow control device as defined in claim 1, wherein the struts form at least two connected rows of undulating loops in the contracted state, the connected rows of undulating loops forming a series of diamond-shaped cells in the expanded state.

28. A flow control device as defined in claim 1, further comprising a plurality of linking struts connecting the valve protector region to the retainer region.

29. A flow control device as defined in claim 28, wherein the linking struts extend in a longitudinal direction from the valve protector region to the retainer region.

30. A flow control device as defined in claim 28, wherein the membrane secures the valve member to the frame.

31. A flow control device as defined in claim 28, wherein the linking struts are flexible.

32. A flow control device as defined in claim 28, wherein the linking struts and the retainer region are formed of the same material.

33. A flow control device as defined in claim 32, wherein the linking struts, retainer region and valve protector region are formed of the same material.

34. A flow control device as defined in claim 28, wherein valve protector region has a first diameter and the retainer region has a second diameter larger than the first diameter, the linking struts extending radially outwardly from the valve protector region to the retainer region.

35. A flow control device as defined in claim 34, wherein the linking struts are curved radially outwardly from the valve protector region to the retainer region.

36. A flow control device as defined in claim 28, wherein the struts of the retainer region form a plurality of zig-zags in the expanded state, each zig-zag having a proximal point and a distal point with a strut extending therebetween, each linking strut being connected to one of the proximal points.

37. A flow control device as defined in claim 28, wherein the struts of the retainer region form a plurality of zig-zags in the expanded sate, each zig-zag having a proximal point and a distal point with a strut extending therebetween, each linking strut being connected to one of the distal points.

38. A flow control device as defined in claim 1, wherein the frame comprises a second retainer region connected to the valve protector region.

39. A flow control device as defined in claim 38, wherein the retainer region is on a first side of the valve protector region and the second retainer region is on a second side of the valve protector region.

40. A flow control device as defined in claim 39, wherein the valve protector region has a diameter less than both of the retainer region and the second retainer region such that the frame has an hourglass-like shape.

41. A flow control device as defined in claim 38, wherein the membrane at least partially covers the second retainer region.

42. A flow control device as defined in claim 1, wherein the retainer region is self-expanding from the contracted state to the expanded state.

43. A flow control device as defined in claim 1, wherein the valve protector region is collapsible from a normal shape to a collapsed shape.

44. A flow control device as defined in claim 43, wherein the valve protector region is self-expandable from the collapsed shape to the normal shape.

45. A flow control device for a bronchial passageway, comprising:

a valve member that regulates fluid flow through the flow control device and has a default shape;

a frame formed of a plurality of interconnected struts configured to engage an interior wall of the bronchial passageway to retain the flow control device in a fixed location therein, the frame being movable from a contracted state suitable for introduction into the bronchial passageway to an expanded state suitable for engaging the interior wall of the bronchial passageway;

a valve protector at least partially surrounding the valve member configured to maintain the valve member in the default shape, the valve protector being collapsible from the default shape to a collapsed shape;

a membrane covering at least a portion of the frame, wherein at least a portion of the flow control device forms a seal with the interior wall of the bronchial passageway when the flow control device is implanted in the bronchial passageway, and wherein the membrane provides a fluid pathway from the seal to the valve member to direct fluid flowing through the bronchial passageway into the valve member.

46. A flow control device as defined in claim 45, wherein the valve member has a mouth that is movable between open and closed configurations, and wherein the valve protector comprises a loop extending around the mouth.

47. A flow control device as defined in claim 46, wherein the mouth has a pair of lips connected at two corners, the loop extending from one corner to the other corner to maintain the distance therebetween.

48. A flow control device as defined in claim 45, wherein the valve protector is formed of a plurality of struts.

49. A flow control device as defined in claim 45, wherein membrane covers at least a portion of the valve protector.

50. A flow control device as defined in claim 45, further comprising a plurality of linking struts connecting the valve protector to the frame.

51. A flow control device as defined in claim 45, wherein the valve protector has a first diameter and the frame has a second diameter, the first diameter being smaller than the second diameter.

52. A flow control device as defined in claim 45, wherein the frame and valve protector are formed of the same material.

53. A flow control device as defined in claim 52, wherein the material is superelastic.

54. A flow control device for a bronchial passageway, comprising:

a valve member that regulates fluid flow through the flow control device;

a frame formed of a plurality of interconnected struts configured to engage an interior wall of the bronchial passageway to retain the flow control device in a fixed

location therein, the frame being movable from a contracted state suitable for introduction into the bronchial passageway to an expanded state suitable for engaging the interior wall of the bronchial passageway;

at least one retention prong extending from the frame and configured to engage the interior wall of the bronchial passageway to resist migration therein.

55. The flow control device of claim 54, wherein the retention prong is fixed to the struts of the frame.

56. The flow control device of claim 55, wherein the struts form a series of undulating loops in the contracted state, the retention prong being disposed between at least a portion of the loops.

57. The flow control device of claim 56, wherein the retention prong is loop shaped in the contracted state, and are expandable to have a V-shape in the expanded state.

58. The flow control device of claim 54, wherein the retention prong comprises an axial post having a first end connected to the frame and a free end opposite the first end.

59. The flow control device of claim 54, wherein the retention prong is configured to project radially outwardly in the expanded state.

60. A flow control device for a bronchial passageway, comprising:

a valve member that regulates fluid flow through the flow control device;

a frame configured to engage an interior wall of the bronchial passageway to retain the flow control device in a fixed location therein, the frame being movable from a contracted state suitable for introduction into the bronchial passageway to an expanded state suitable for engaging the interior wall of the bronchial passageway; and

a membrane covering at least a portion of the frame, wherein at least a portion of the flow control device forms a seal with the interior wall of the bronchial passageway when the flow control device is implanted in the bronchial passageway, and wherein the membrane provides a fluid pathway from the seal to the valve member to direct fluid flowing through the bronchial passageway into the valve member.

61. A flow control device as defined in claim 60, wherein the membrane has a thickness of about .001-.010 inch.

62. A flow control device as defined in claim 60, wherein the membrane encapsulates the struts.

63. A flow control device as defined in claim 60, wherein the membrane is positioned on top of the struts.

64. A flow control device as defined in claim 60, wherein the membrane is

expandable and collapsible with the frame.

65. A flow control device as defined in claim 60 wherein the membrane is elastic.

66. A flow control device for a bronchial passageway, comprising:

a valve member that regulates fluid flow through the flow control device;

a frame coupled to the valve member; and

a membrane attached to the frame, wherein at least a portion of the flow control device forms a seal with the interior wall of the bronchial passageway when the flow control device is implanted in the bronchial passageway, and wherein the membrane forms a fluid pathway from the seal into the valve member to direct fluid flowing through the bronchial passageway into the valve member.

67. A flow control device as defined in claim 66, wherein the frame forms a seal with the interior wall of the bronchial passageway.

68. A flow control device as defined in claim 66, wherein the membrane forms a seal with the interior wall of the bronchial passageway.

69. A flow control device as defined in claim 66, wherein the both the frame and the membrane form a seal with the interior wall of the bronchial passageway.